UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,522	03/26/2004	Dale L. Benedict	02008.00031	1193

7590 11/22/2005

Steven Thrasher
391 Sandhill Dr.
Richardson, TX 75080

EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,522	BENEDICT ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment filed 6 September 2005 has been received and entered. Claims 1, 2 and 6-12 have been amended. **Claims 1-12 are pending** to which the following grounds of rejection are or **remain applicable**.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention. D-Mannose capsules are known and have been used by the public for, *inter alia*, urinary tract infections. See D-Mannose 500 mg capsules from NOWfoods.com enclosed herein (http://www.nowfoods.com/?actikon=itemdetail&item_id=40537&TPL_NAME=printview.tpl)

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (The Journal of Biological Chemistry, 12/13/1996)

Morris et al. teach a human amniotic fluid-derived glycoprotein, glycodelin-A (GdA), which has a high mannose content, inhibits gamete binding in an established sperm-egg binding system, thus inhibiting contraception (see abstract).

It fails to teach administering D-mannose to inhibit the interaction.

It would have been obvious to administer D-mannose to inhibit contraception. Motivation to employ D-mannose would come from the teachings of the prior art wherein GdA, having a high mannose content, inhibits gamete binding. Although the prior art does not teach inhibition of conception specifically, conception is not possible when gamete binding does not occur, thus inhibiting conception.

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (J. Androl 1995)

Chen et al. teach that almost 50% of spermatozoa, which was bound to the zona (pellucida) of an egg, detached from it when d-mannosylated albumin (DMA) was introduced to the incubation medium. Chen et al. teach inhibition of fertilization in vitro. The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose causes spermatozoa to detach from the egg in vitro, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of spermatozoa-zona pellucida binding with in vitro methods as recited by Chen et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–egg binding would occur (intravaginally) to inhibit

conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cornwall et al. (Biology of Reproduction, 1991)

Cornwall et al. teach that D-mannose incubated with mouse spermatozoa resulted in a dose-dependent decrease in the number of spermatozoa bound per egg without a deleterious effect of sperm motility.

The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose causes a reduction in the number of spermatozoa bound per egg in vitro, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of

administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of sperm-egg binding with in vitro methods as recited by Cornwall et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–egg binding would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (Human Reproduction, 1993)

Mori et al. teach that in the presence of D-mannose, sperm penetration through the human zona pellucida was completely blocked.

The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose blocks sperm penetration through the zona pellucida, required for conception, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary

skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of sperm-egg binding with in vitro methods as recited by Mori et al. above. One of ordinary skill in the art would optimize the teachings of the prior art and deliver D-mannose directly to the area that spermatozoa–zona pellucida penetration would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Claims 1-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida-Komiya et al. (Zygote, 1999)

Yoshida-Komiya et al. teach significantly fewer sperm were bound per egg in the presence of competitive inhibitors of mannosidase or anti-mannose binding protein. Among the sugars examined, D-mannose was the most potent inhibitor causing 70% reduction in the number of sperm bound per egg (see abstract).

The instant claims are drawn to inhibition of fertilization (conception) in vivo. Since it is known that D-mannose causes a reduction in the number of spermatozoa bound per egg in vitro, it would have been obvious to administer the D-mannose in vivo to prevent conception. Regarding the dose of D-mannose, as anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. The specific safe and effective amount will be vary, with such factors as the particular condition being treated, the physical condition of the patient, the duration of treatment, the nature of the concurrent therapy (if any), the specific dosage form to be used, the carrier employed, the solubility of the formula therein and the dosage regimen desired for the composition. Regarding the mode of administration of D-mannose, modes of administration are art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to optimize them from the teachings of the prior art. It would have been obvious to administer the D-mannose intravaginally. Motivation would come from the knowledge that there is inhibition of sperm-egg binding with in vitro methods as recited by Yoshida-Komiya et al. above. One of ordinary skill in the art would optimize the teachings of the

prior art and deliver D-mannose directly to the area that spermatozoa–egg binding would occur (intravaginally) to inhibit conception. Regarding the co-administration of another contraceptive, it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *In re Kerkhoven* 205 USPQ 1069. The idea for combining said compositions flows logically from their having been individually taught in the prior art. *In re Crockett* 126 USPQ 186, 188. See also *In re Shannon* 148 USPQ 504 (one step laminate is obvious from two step laminate).

Statutory Double Patenting

Claim 12 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,753,319 B2. This is a double patenting rejection.

Non-Statutory Double Patenting

Claims 1, 3 and 4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/921748. This is a provisional obviousness-type double patenting rejection. The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claims 1-3 require the D-Mannose to be placed in a natural habitat of a targeted animal or in a natural food form or in a drinking supply. Instant claims 1, 3 and 4 are broadly inclusive thereof because they are drawn to inhibiting

conception of a female comprising administration of D-Mannose in the form of a capsule or tablet or mixed with a food or drink. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Response to Arguments

Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Regarding the amendments to the claims, applicant must point out how the amendment to the claims avoids the references applied against the claims. Applicant cites a discussion with the examiner in the remarks submitted 6 September 2005. The discussion was informal and was not a formal interview. The examiner did not discuss the merits of the case. The telephone call was to inquire as to the status of the case.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

11/15/2005

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600